REMARKS

Claims 3, 4, 8, 9, 19-22, 25-26, 38-40, 42, 74-76, 78, 102, 104, 108 and 111-114 remain in this case.

The amendments to the claims eliminate the need to prosecute the parent application, application number 09/740,597. Applicant therefore intends to permit the parent application to become abandoned by not responding to the outstanding Office Action mailed 6 June 2005.

Claims 3, 4, 9, 11, 23, 25, 26, 38-40, 42, 74-76, 78 and 108 have been rejected as obvious over Khosravi (U.S. Patent number 5,824,054) in view of Khosravi (U.S. Patent number 5,824,053) and Herzog (PCT publication number WO 98/08482). Claims 8, 41 and 77 were rejected as obvious over Khosravi '054 in view of Khosravi (U.S. Patent number 5,824,053), Herzog '482 and Kropf '849. Claims 19-22 were rejected as obvious over Khosravi '054 in view of Khosravi (U.S. Patent number 5,824,053), Herzog '482 and Ragheb '904. Claims 102 and 104 were rejected as obvious over Khosravi '054 in view of Khosravi (U.S. Patent number 5,824,053), Herzog '482 and Hansen '352.

Claims 3, 4, 9, 11, 23, 25, 26, 38-40, 42, 74-76, 78 and 108 have also been rejected as obvious over Fogarty (U.S. Patent number 6,585,760) in view of Herzog (PCT publication number WO 98/08482). This application and the Fogarty patent were, at the time the invention of this application was made, both owned by Vascular Architects, Inc. Therefore, this ground of rejection is overcome.

The Cited Art

Khosravi U.S. Patent No. 5,824,054 shows a graft stent 10 made of a coiled sheet 11 of lattice or mesh to which a biocompatible graft material 12 is affixed. Graft material may have a desired permeability and may be impregnated with one or more drugs to effect a desired treatment. (Column 4, lines 61-66.) Graft stent 10 is wrapped on to itself like a roll of tape. Figures 5A-5C show placement of graft stent 10 into a body lumen 100 to treat an aneurysm 101. The graft stent 10 is expanded by a balloon 47 and is locked into its enlarged diameter configuration by teeth 15 engaging openings 16. (See figure 1 and column 5, lines 32-40.) The device is stated to be useful to "stem blood loss through an arterio-venous fistula, or provide a positive seal at the ends of a graft to reduce bypass flow." (Column 2, lines 31-35; column 3, lines 3-8.)

Khosravi U.S. Patent No. 5,824,053 discloses the helically coiled stent 10 made from a flat sheet of material, such as a shape memory alloy. Openings 14 are formed in the sheet to promote tissue ingrowth.

Herzog PCT Publication No. WO 98/08482 discloses several embodiments:

- The surface of, for example, a stent, catheter, etc. is coated with a polymeric coating containing sodium nitroprusside. The coating permits the NO to diffuse into the blood or body tissue. See page 6, last paragraph. The coating can be formed by immersing the stent, catheter, etc. into a solution or colloidal suspension including the polymer and sodium nitroprusside. See page 13, first full paragraph.
- Figure 2, page 15 discloses a stent and grooves on the inner wall. Sodium nitroprusside can be deposited in the grooves and covered by a polymer coating.
- Page 19, example 6 of Herzog discloses a metal stent with grooves along its length. A nitroprusside powder is placed in the grooves and the stent is coated with the PVC solution. The number of coatings, and thus the thickness of the PVC, can be changed to obtain the desired flux of NO.

Hanson U.S. Patent No. 5,399,352 discloses a drug delivery device 10 comprising a first element 4 and a second element 24. The first element comprises an elongate tubular segment 5 comprising a porous clinical vascular graft attached at each end to a severed artery 2. Tubular segment 5 includes a porous portion 28. Porous portion 28 is surrounded by second element 24. A reservoir 20 is formed between porous portion 28 and second element 24. Reservoir 20 can be non-fillable or supplied with an agent through tubing 30. See column 7, line 32-column 8, line 20. This permits the agent to be delivered into the blood flowing through tubular segment 5 so that it can pass with the blood into the interior of the artery.

Kropf U.S. Patent No. 4,760,849 discloses a planar blank which can be made into a coil spring useful as a filter for thromboses. The coil spring has apertures to facilitate ingrowth of tissue into the spring material. See column 1, lines 61-63 and column 2, lines 51-55. This reference only discloses a stent. It teaches away from adding a graft material because a stated intention of the invention is to permit tissue ingrowth through the apertures. There is no recognition that the addition of a graft material would be useful or possible.

Ragheb U.S. Patent No. 5,873,904 discloses a medical device 10 including a structure 12, typically a vascular stent 12, composed of an elastic/non-elastic, biodegradable/non-biodegradable base material 14, such as stainless steel, nitinol, polymers, etc. Stent 12 is shown to have several layers of materials coated thereon. At least one layer 18 of a bioactive material is on the surface of stent 12. An outer porous layer 20 is on layer 18 to provide controlled release of the bioactive material. A porous/non-porous layer 16 may be used between the bioactive layer 18 and stent 12. A second bioactive layer 22

may be used between porous layer 20 and bioactive layer 18; if so, an inner porous layer 24 may be used between the bioactive layers 18, 22.

The Cited Art Distinguished

Claim 38 recites in part the following.

> "a coiled body extending along a generally helical path ...;
> a coiled sleeve of porous material extending along the generally helical path, the material having an inner surface ... defining the sleeve interior containing the coiled body; and
> a dispensable, biologically active agent within the sleeve interior, ..."

1. The art fails to disclose the claimed coiled sleeve of porous material extending along the same helical path as the coiled body. The body of Khosravi '054 does not extend along the helical path. The body of Khosravi '053 extends along a helical path but there is no suggestion about employing a graft material as in Khosravi '054. Herzog discloses a coating but nothing about a helically extending structure.

There would have been no reason to modify Khosravi '054 to make a helically extending body and provide a helically extending sleeve with open regions in its interior. One reviewing the Khosravi '054 and Khosravi '053 patents is provided no guidance as to the advantages of or desirability to do so. Rather, the fact that these two Khosravi patents were filed on the same day and issued on the same day indicates the separateness of these two inventions. That is, there is no evidence to support a position that the graft material be a coiled sleeve and extend along the same generally helical path as the body.

2. The use of the coiled sleeve in conjunction with the coiled body, both extending along the same generally helical path, provides significant advantages during use. For example, the coiled sleeve follows the coiled body to readily accommodate changes in the length of the coiled body. This permits the coiled body to relatively freely change its diameter and length without the sleeve binding or bunching up, as it could if it were a simple tubular sleeve (as the prior art teaches). The fact that the coiled sleeve follows the coiled body also enhances the flexibility of the prosthesis, an important consideration when used in parts of the body that undergo great amounts of flexion, such as along the knee. In addition, helical gaps may be provided between the turns of the prosthesis to accommodate side branch flow.

Accordingly, claim 38 is allowable over the cited art.

Method **claim 74** is allowable for similar reasons.

The **dependent claims** are directed to specific novel subfeatures of the invention and are allowable that reason is well as by depending from novel parent claims. For example, **claim 111** recites in part that the sleeve interior comprises open spaces not occupied by the coiled body. This feature, coupled with the feature of the coiled sleeve following the coiled body, it is not disclosed in nor made obvious by the cited art; this aspect of the invention of provides additional advantages in that it permits the prosthesis to be constructed to permit relatively large amounts of the biologically active agent to be housed within the prosthesis. **Claim 113** is allowable for similar reasons.

CONCLUSION

In light of the above remarks and the amendments to the claims, applicant submits that the application is in condition for allowance and action to that end is urged. If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

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James F. Hann, Registration No. 29,719

HAYNES BEFFEL & WOLFELD LLP
P.O. Box 366
Half Moon Bay, California 94019
Phone: 650-712-0340
Fax: 650-712-0263
JFH:pfh